DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 6-773/S-036/(b)(4

Wyeth Pharmaceuticals Inc.
Attention: Tracy Rockney
Director, Worldwide Regulatory Affairs
P.O. Box 8299
Philadelphia, PA 19101-8299

Dear Ms. Rockney:

Please refer to your supplemental new drug applications dated April 27, 2001 (S-036), and June 14, 2001 (S-037) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Artane (trihexyphenidyl Hydrochloride) 2 mg and 5 mg Tablets and 2 mg/5 ml Elixir.

We additionally acknowledge receipt of your amendment dated July 3, 2001 to S-037.

Supplemental application, S-036, submitted under "Changes Being Effected" provides for the following revisions to the labeling:

1. Changed the section title from **CLINICAL ACTIONS** to **CLINICAL PHARMACOLOGY**.
2. Changed the section title from **INDICATIONS** to **INDICATIONS AND USAGE**.
3. Added a **CONTRAINDICATIONS** section.
4. Added several safety related revisions to the **WARNINGS**, **PRECAUTIONS**, and **ADVERSE REACTIONS** sections.
5. Added new subsections entitled **Information for Patients**, **Drug Interactions, Nursing Mothers**, and **Pediatric Use** to the **PRECAUTIONS** section.
6. Added new sections entitled **DRUG ABUSE AND DEPENDENCE** and **OVERDOSAGE**.
7. Minor editorial changes.

We have completed the review of this supplemental application, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the draft labeling submitted on April 27, 2001. Accordingly, this supplemental application is approved effective on the date of this letter.

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The remainder of your revisions are acceptable.

Please submit 20 paper copies of the final printed labeling (to each application) ten of which are individually mounted on heavy weight paper or similar material. Alternatively, you may submit the FPL electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDAs* (January 1999).

If additional information relating to the safety or effectiveness of these drugs becomes available, revision of the labeling may be required.

If you have any questions, call Mr. Paul David, R.Ph., Senior Regulatory Project Manager, at (301) 594-5530.

Sincerely,

{See appended electronic signature page}

Russell Katz, M.D.
Director
Division of Neuropharmacological Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Russell Katz

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